

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, et al.,

Plaintiffs and Relator,

-against-

NOVARTIS PHARMACEUTICALS  
CORPORATION, et al.,

Defendants.

**11 CIV. 8196 (CM) (JCF)**

**DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S  
REQUESTS TO CHARGE**

Pursuant to Federal Rule of Civil Procedure 51(a)(1) and Part V(C)(i) of this Court's Individual Practices and Procedures, Defendant Novartis Pharmaceuticals Corporation respectfully submits the following requests to charge.<sup>1</sup>

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<sup>1</sup> Pursuant to Federal Rule of Civil Procedure 51(a)(2), Novartis reserves the right to submit additional proposed instructions, or to withdraw or to amend the included instructions, as a result of the introduction of issues at trial it cannot now reasonably anticipate or based upon subsequent decisions of the Court, including the resolution of in limine and Daubert motions.

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**I. GENERAL INSTRUCTIONS**

**Jury Instruction No. 1: Juror Attentiveness**

Ladies and gentlemen, before you begin your deliberations, I now am going to instruct you on the law. You must pay close attention and I will be as clear as possible.

It has been obvious to me and counsel that until now you have faithfully discharged your duty to listen carefully and observe each witness who testified. Your interest never flagged, and you have followed the testimony with close attention.

I ask you to give me that same careful attention as I instruct you on the law.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 71-1 (Lexis 2015).

**Jury Instruction No. 2:**      **Overview of Parties**

This case involves the False Claims Act. The False Claims Act allows a private citizen to bring an action in the name of the federal government against a person or entity who allegedly violates the Act. The private citizen who brings the action is called a “relator.” In this case, David Kester initially brought this case, and he is the Relator. If you award damages to the United States, the Court will award a portion of the recovery to the Relator, but the majority of damages are returned to the United States Treasury.

After the case is filed by the Relator, the federal and state governments have the opportunity to investigate the allegations. If they so choose, the federal government may intervene in the case and assume the primary responsibility for litigating it.

The Defendant, Novartis Pharmaceuticals Corporation, is a company based in East Hanover, New Jersey that manufactures and sells medications. This case concerns two prescription drugs, called Exjade and Myfortic, which are manufactured by Novartis.

[Exjade phase: This trial has been split into two phases, one for Exjade and one for Myfortic. We are now in the Exjade phase of the case, and the Myfortic phase of the case will come next. In this phase of the case, the United States and some of the states intervened against Novartis for the Exjade claims submitted by BioScrip and Accredo, but not US Bioservices. Mr. Kester continues to represent the United States and these intervening states for Exjade claims submitted by US Bioservices. Other states have declined to intervene in this case, and Mr. Kester is litigating on their behalf for Exjade claims submitted by BioScrip, Accredo and US Bioservices. I will refer to the

United States, the intervening states, and the states represented by Mr. Kester as the Plaintiffs.]

[Myfortic phase: This trial has been split into two phases, one for Exjade and one for Myfortic. We have already completed the Exjade phase of the case, and we are now in the Myfortic phase of the case. In this phase of the case, the United States has intervened against Novartis for the Myfortic claims submitted by Twenty Ten, Kilgore's, Bryant's, Baylor and/or Transcript. While Mr. Kester is still a party, the United States is the party primarily responsible for litigating this Myfortic phase for the federal government. Mr. Kester continues to represent states for Myfortic claims by the five Myfortic specialty pharmacies. I will refer to the United States and the states represented by Mr. Kester as the Plaintiffs.]

Because the various state governments and federal government may have decided to intervene or not to intervene for any number of reasons that are not related to the strength of their case, you should draw no inferences from the fact that the governments intervened or declined to intervene.

AUTHORITY: Adapted from Charge of Hon. William H. Pauley III, Trial Tr. 1466:16-1467:3, U.S. ex rel. Feldman v. Van Gorp, No. 03 Civ. 8135 (S.D.N.Y. July 22, 2010) (Ex. 1), aff'd 697 F.3d 78 (2d Cir. 2012); Jury Instruction No. 22, U.S. ex rel. Bunk v. Gosselin Worldwide Moving, N.V., No. 1:02-cv-1168 (E.D. Va. Aug. 1, 2014) (Ex. 2) (ECF No. 1312-3), appeal docketed, Nos. 15-1088, 15-1207 (4th Cir. 2015); District Court's Set of Combined Proposed Jury Instruction, Jury Instruction No. 5, U.S. ex rel. Rigsby v. State Farm, No. 1:06-cv-433 (S.D. Miss. Apr. 8, 2013) (Ex. 3) (ECF No. 1125); Concluding Jury Instruction No. 13 at 15, U.S. ex rel. Hooper v. Lockheed Martin Corp., No. CV 08-561 (C.D. Cal. Mar. 26, 2014) (Ex. 4) (ECF No. 453-1).

**Jury Instruction No. 3:**      **Role of the Court**

Members of the jury, now that you have heard the evidence and the arguments of counsel, it's my duty to give you the instructions as to the law that's applicable in the case.

And it is your duty as jurors to follow the law as stated in these instructions and to apply the rules of law to the facts as you find them to be from the evidence in the case.

Now, you're not to single out any one instruction as stating the law. You have to consider the instructions as a whole. You are also not to be concerned with the wisdom of any rule of law that I state. It is your sworn duty to issue a verdict based upon the law as instructed by the Court regardless of any opinion you may have about what the law ought to be.

AUTHORITY: Charge of Hon. Colleen McMahon, Trial Tr. 2557:6-19, Mendez v. Starwood Hotels & Resorts Worldwide, Inc., No. 08 Civ. 4967 (S.D.N.Y. Mar. 8, 2010) (Ex. 5).

**Jury Instruction No. 4:**      **Role of the Jury**

As members of the jury, you are the sole and exclusive judges of the facts. You pass upon the evidence. You determine the credibility of the witnesses. You resolve such conflicts as there may be in the testimony. You draw whatever reasonable inferences you decide to draw from the facts as you have determined them, and you determine the weight of the evidence.

In determining these issues, no one may invade your province or functions as jurors. In order for you to determine the facts, you must rely upon your own recollection of the evidence. What the lawyers have said in their opening statements, in their closing arguments, in their objections or in their questions is not evidence. What I have said—or what I say in these instructions—about a fact issue is not evidence. In connection with this, you should bear in mind that a question put to a witness is never evidence; it is only the answer that is evidence. But you may not consider any answer that I directed you to disregard or that I directed to be struck from the record. Do not consider such answers.

Since you are the sole and exclusive judges of the facts, I do not mean to indicate any opinion as to the facts or what your verdict should be. The rulings I have made during the trial are not any indication regarding my views of what your decision should be as to whether or not Plaintiffs have proven their case.

I also ask you to draw no inference from the fact that upon occasion I asked questions of certain witnesses. These questions were only intended for clarification or to expedite matters and certainly were not intended to suggest any opinions on my part as to the verdict you should render, or whether any of the witnesses

may have been more credible than any of the other witnesses. You are expressly to understand that the Court has no opinion as to the verdict you should render in this case.

As to the facts, ladies and gentlemen, you are the exclusive judges. You are to perform the duty of finding the facts without bias or prejudice to any party.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 71-3 (Lexis 2015).

**Jury Instruction No. 5:**      **Juror Oath**

In determining the facts, you are reminded that you took an oath to render judgment impartially and fairly, without prejudice or sympathy and without fear, solely upon the evidence in the case and the applicable law. I know that you will do this and reach a just and true verdict.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 71-4 (Lexis 2015).

**Jury Instruction No. 6:**      **Conduct of Counsel**

It is the duty of the attorney on each side of a case to object when the other side offers testimony or other evidence that the attorney believes is not properly admissible. Counsel also have the right and duty to ask the Court to make rulings of law and to request conferences at the side bar out of the hearing of the jury. All those questions of law must be decided by me, the Court. You should not show any prejudice against an attorney or his client because the attorney objected to the admissibility of evidence, or asked for a conference out of the hearing of the jury or asked the Court for a ruling on the law.

As I have already indicated, my rulings on the admissibility of evidence do not, unless expressly stated by me, indicate any opinion as to the weight or effect of such evidence. You are the sole judges of the credibility of all witnesses and the weight and effect of all evidence.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 71-6 (Lexis 2015).

**Jury Instruction No. 7:**      **Sympathy**

Under your oath as jurors you are not to be swayed by sympathy. You should be guided solely by the evidence presented during the trial, without regard to the consequences of your decision.

You have been chosen to try the issues of fact and reach a verdict on the basis of the evidence or lack of evidence. If you let sympathy interfere with your clear thinking there is a risk that you will not arrive at a just verdict. All parties to a civil lawsuit are entitled to a fair trial. You must make a fair and impartial decision so that you will arrive at the just verdict.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 71-10 (Lexis 2015).

**Jury Instruction No. 8:**      **Corporate Parties**

In this case the defendant, Novartis, is a corporation. The mere fact that a party is a corporation does not mean it is entitled to any lesser consideration by you. All litigants are equal before the law, and corporations, big or small, are entitled to the same fair consideration as you would give any other individual party.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 72-1 (Lexis 2015).

**Jury Instruction No. 9:      Corporate Responsibility**

A corporation is a creation of state law and can act only through its agents—that is, its employees, officers or authorized representatives. In order to find that the act of an agent was binding on the corporation you must find that the agent had authority to act in the manner in which he or she is alleged to have acted.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 72-2 (Lexis 2015).

**Jury Instruction No. 10:     Publicity**

Your verdict must be based solely on the evidence presented in this courtroom in accordance with my instructions. You must completely disregard any report that you have read in the press, seen on television, or heard on the radio. Indeed, it would be unfair to consider such reports, since they are not evidence and the parties have no opportunity of contradicting their accuracy or otherwise explaining them. In short, it would be a violation of your oath as jurors to allow yourselves to be influenced in any manner by such publicity.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 71-14 (Lexis 2015).

**Jury Instruction No. 11: Duty of Confidentiality**

It is your duty as jurors to keep your views and deliberations confidential. Your views on the parties or any aspect of this trial may not be disclosed to any member of the public. You must also not discuss this case with others, including your friends and family. This duty of confidentiality extends to all communications, including conversations, text messages and other digital messaging, emails, blogs and postings on Internet sites.

AUTHORITY: Adapted from Ninth Circuit Manual of Model Jury Instructions—Civil, Instruction 1.12 (Lexis 2007); cf. Third Circuit Manual of Model Jury Instruction—Civil, Instruction 1.3 (West 2015); Fifth Circuit Pattern Jury Instructions—Civil, Instruction 1.1 (West 2014).

**Jury Instruction No. 12:**     **Burden of Proof—General Instruction**

This is a civil case and as such the Plaintiffs—the federal government, the states and the Relator—have the burden of proving the material allegations of their complaint by a preponderance of the evidence, except for their claims for common law fraud and claims for civil conspiracy, which have an even higher burden of proof that I will discuss later.

If after considering all of the testimony you are satisfied that Plaintiffs have carried their burden on each element as to which they have the burden of proof, then you must find for Plaintiffs on their claims. If after such consideration you find the testimony of both parties to be in balance or equally probable, then Plaintiffs have failed to sustain their burden and you must find for Novartis. If you are not satisfied that Plaintiffs have met their burden regarding any element as to which they have the burden of proof, then you must find for Novartis.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 73-1 (Lexis 2015).

**Jury Instruction No. 13: Burden of Proof—Preponderance of the Evidence**

Other than the claims for common law fraud and civil conspiracy, which have a higher burden of proof that I will explain later, Plaintiffs' burden of proof is by a preponderance of the evidence. Plaintiffs therefore have the burden of proving every disputed element of their claims to you by a preponderance of the evidence. If you conclude that a Plaintiff has failed to establish any element on which it has the burden of proof by a preponderance of the evidence, you must decide against that Plaintiff on the issue you are considering.

What does a "preponderance of evidence" mean? To establish a fact by a preponderance of the evidence means to prove that the fact is more likely true than not true. A preponderance of the evidence means the greater weight of the evidence. It refers to the quality and persuasiveness of the evidence, not to the number of witnesses or documents. In determining whether an element has been proved by a preponderance of the evidence, you may consider the relevant testimony of all witnesses, regardless of who may have called them, and all the relevant exhibits received in evidence, regardless of who may have produced them.

If you find that the credible evidence on an element is evenly divided between the parties—that it is equally probable that one side is right as it is that the other side is right—then you must decide that element has not been met by that Plaintiff. That is because the party bearing this burden must prove more than simple equality of evidence—he must prove the element at issue by a preponderance of the evidence. On the other hand, the party with this burden of proof need prove no more than a preponderance. So long as you find that the scales tip, however slightly, in favor of the party with this burden of proof—that what the party claims is more likely true than not

true—then that element will have been proved by a preponderance of evidence. If you find that Plaintiffs have failed to meet their burden of proof with respect to even one element of the claim, you must find in favor of Novartis.

Some of you may have heard of proof beyond a reasonable doubt, which is the proper standard of proof in a criminal trial. That requirement does not apply to a civil case such as this and you should put it out of your mind.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 73-2 (Lexis 2015).

## **II. GENERAL EVIDENCE INSTRUCTIONS**

### **Jury Instruction No. 14: What Is and Is Not Evidence**

The evidence in this case is the sworn testimony of the witnesses, the exhibits received in evidence, stipulations and judicially noticed facts.

By contrast, the question of a lawyer is not to be considered by you as evidence. It is the witnesses' answers that are evidence, not the questions. At times, a lawyer may have incorporated into a question a statement that assumed certain facts to be true, and asked the witness if the statement was true. If the witness denied the truth of the statement, and if there is no evidence in the record proving that assumed fact to be true, then you may not consider it to be true simply because it was contained in the lawyer's question.

The famous example of this is the lawyer's question of a married witness: "When did you stop beating your wife?" You would not be permitted to consider as true the assumed fact that he ever beat his wife, unless the witness himself indicated he had, or unless there was some other evidence in the record that he had beaten his wife.

Testimony that has been stricken or excluded is not evidence and may not be considered by you in rendering your verdict. Also, if certain testimony or other evidence was received for a limited purpose—such as for the purpose of assessing a witness's credibility or a witness's state of mind—you must follow the limiting instructions I have given.

Putting aside any lawyers called to the stand to testify about facts and circumstances they experienced, the lawyers presenting this case are not witnesses. Arguments by lawyers are not evidence. What they have said to you in their opening statements and in their summations is intended to help you understand the evidence to

reach your verdict. However, if your recollection of the facts differs from the lawyers' arguments, it is your recollection that controls.

You should treat the lawyers that were called to the stand to testify about facts and circumstances they experienced as you treat all other witnesses who testified. You must consider and evaluate their testimony as you do for witnesses who are not lawyers.

To constitute evidence that may be considered by you, exhibits must be received in evidence. Exhibits marked for identification but not admitted are not evidence, nor are materials brought forth only to refresh a witness's recollection.

Finally, statements that I may have made concerning the quality of the evidence do not constitute evidence.

It is for you alone to decide the weight, if any, to be given to the testimony you have heard and the exhibits you have seen.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 74-1 (Lexis 2015).

**Jury Instruction No. 15: Outside Research Is Prohibited**

You may only consider evidence admitted at trial. Do not do any research into the parties, witnesses or any involved company, alleged facts, claims or any other matter presented throughout the course of this trial. You may not consult books, dictionaries, newspapers, internet sites, internet search engines, or any other media for the purpose of supplementing the information you are given here, and you may not make any investigation about the case on your own. Like trial publicity, those sources are not evidence, their reliability is unknown and the parties would have no opportunity to address the information contained in those sources. Allowing yourselves to be influenced in any manner by those sources is a violation of your oath as jurors.

AUTHORITY: Adapted from Ninth Circuit Manual of Model Jury Instructions—Civil, Instruction 1.12 (Lexis 2007); see Third Circuit Manual of Model Jury Instruction—Civil, Instruction 1.3 (West 2015); Fifth Circuit Pattern Jury Instructions—Civil, Instruction 1.1 (West 2014).

**Jury Instruction No. 16:     Evidence for Limited Purpose**

Throughout this trial, I have cautioned you that some evidence may be admitted for a limited purpose only, such as a witness's state of mind rather than for the truth. I remind you that you must consider that evidence only for that limited purpose and for no other.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 74-1 (Lexis 2015).

**Jury Instruction No. 17: Direct and Circumstantial Evidence**

There are two types of evidence that you may properly use in reaching your verdict.

One type of evidence is direct evidence. Direct evidence is when a witness testifies about something he knows by virtue of his own senses—something he has seen, felt, touched, or heard. Direct evidence may also be in the form of an exhibit when the fact to be proved is its present existence or condition.

The other type of evidence is circumstantial evidence. This is evidence that tends to prove a disputed fact by proof of other facts. There is a simple example of circumstantial evidence that is often used in this courthouse.

Assume that when you came into the courthouse this morning the sun was shining and it was a nice day. Assume that the courtroom blinds were drawn and you could not look outside. As you were sitting here, someone walked in with an umbrella that was dripping wet. Then a few minutes later another person also entered with a wet umbrella. Now, you cannot look outside of the courtroom and you cannot see whether or not it is raining. So you have no direct evidence of that fact. But on the combination of facts that I have asked you to assume, it would be reasonable and logical for you to conclude that it had been raining.

That is all there is to circumstantial evidence. You infer on the basis of reason and experience and common sense from one established fact the existence or non-existence of some other fact.

Circumstantial evidence is of no less value than direct evidence, for it is a general rule that the law makes no distinction between direct evidence and circumstantial

evidence but simply requires that your verdict must be based on a preponderance of all the evidence presented.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 74-2 (Lexis 2015).

**Jury Instruction No. 18:     Depositions**

Some of the testimony before you is in the form of depositions which have been received in evidence. You may have heard references to deposition testimony in questions, but unless that deposition testimony was specifically received in evidence, it should not be considered by you as evidence. A deposition is simply a procedure where prior to trial the attorneys for one or both sides may question a witness or an adversary party under oath before a court stenographer. This is part of the pretrial discovery, and each side is entitled to take depositions. You may consider the testimony of a witness given at a deposition according to the same standards you would use to evaluate the testimony of a witness given at trial.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 74-14 (Lexis 2015).

**Jury Instruction No. 19: Credibility of Witnesses**

In deciding the facts in this case, you may have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says, or part of it, or none of it.

In considering the testimony of any witness, you may take into account:

- (1) the opportunity and ability of the witness to see or hear or know the things testified to;
- (2) the witness's memory;
- (3) the witness's manner while testifying;
- (4) the witness's interest in the outcome of the case and any bias or prejudice;
- (5) whether other evidence contradicted the witness's testimony;
- (6) the reasonableness of the witness's testimony in light of all the evidence; and
- (7) any other factors that bear on believability.

The weight of the evidence as to a fact does not necessarily depend on the number of witnesses who testify.

AUTHORITY: Adapted from Ninth Circuit Manual of Model Jury Instructions—Civil, Instruction 1.11 (West 2007); see Third Circuit Manual of Model Jury Instruction—Civil, Instruction 1.17 (West 2015); Seventh Circuit Federal Jury Instructions—Civil, Instruction 1.13 (West 2010).

**Jury Instruction No. 20: Expert Witnesses—Generally**

In this case, I have permitted certain witnesses to express their opinions about matters that are in issue. A witness may be permitted to testify to an opinion on those matters about which he or she has special knowledge, skill, experience and training. Such testimony is presented to you on the theory that someone who is experienced and knowledgeable in the field can assist you in understanding the evidence or in reaching an independent decision on the facts.

In weighing this opinion testimony, you may consider the witness's qualifications, his or her opinions, the reasons for testifying, as well as all of the other considerations that ordinarily apply when you are deciding whether or not to believe a witness's testimony. You may give the opinion testimony whatever weight, if any, you find it deserves in light of all the evidence in this case. You should not, however, accept opinion testimony merely because I allowed the witness to testify concerning his or her opinion. Nor should you substitute it for your own reason, judgment and common sense. The determination of the facts in this case rests solely with you.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 76-9 (Lexis 2015) (citing United States v. Simon, 425 F.2d 796 (2d Cir. 1969)).

**Jury Instruction No. 21: Conflicting Expert Testimony**

You have heard testimony of witnesses who have been called by both sides to give their opinion as experts regarding various issues.

The testimony of these witnesses is in conflict. They disagree. You must remember that you are the sole trier of the facts and their testimony relates to questions of fact, so, it is your job to resolve the disagreement.

The way that you resolve the conflict between these witnesses is the same as the way that you decide other fact questions and just as you decide whether to believe ordinary witnesses. In addition, you should consider the soundness of each opinion, reasons for the opinion and the witness's motive, if any, for testifying.

You may give the testimony of each of these witnesses such weight, if any, that you think it deserves in the light of all the evidence. You should not permit a witness's opinion testimony to be a substitute for your own reason, judgment and common sense.

You may reject the testimony of any opinion witness in whole or in part, if you conclude the reasons given in support of an opinion are unsound or, if you, for other reasons, do not believe the witness. The determination of the facts in this case rests solely with you.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 76-10 (Lexis 2015) (citing United States v. Bohle, 475 F.2d 872, 874 (2d Cir. 1973)).

**Jury Instruction No. 22: Inferences**

During the trial you have heard the attorneys use the term “inference,” and in their arguments they have asked you to infer, on the basis of your reason, experience, and common sense, from one or more established facts, the existence of some other fact.

An inference is not a suspicion or a guess. It is a reasoned, logical conclusion that a disputed fact exists on the basis of another fact which has been shown to exist.

There are times when different inferences may be drawn from facts, whether proved by direct or circumstantial evidence. Plaintiffs ask you to draw one set of inferences, while the defense asks you to draw another. It is for you, and you alone, to decide what inferences you will draw.

The process of drawing inferences from facts in evidence is not a matter of guesswork or speculation. An inference is a deduction or conclusion which you, the jury, are permitted to draw—but not required to draw—from the facts which have been established by either direct or circumstantial evidence. In drawing inferences, you should exercise your common sense.

So, while you are considering the evidence presented to you, you are permitted to draw, from the facts which you find to be proven, such reasonable inferences as would be justified in light of your experience.

AUTHORITY: Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Civil, Instruction 75-1 (Lexis 2015).

**Jury Instruction No. 23:**     **[Myfortic Phase Only: Attorney-Client Privilege]**

Under the law, a party generally has no obligation to testify or to present any evidence about the advice the party receives from its attorneys, because attorney-client communications are protected from disclosure. This is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and the administration of justice. In the Exjade phase of the case, Novartis waived this attorney-client privilege, meaning that it chose to present testimony and evidence regarding the legal advice it received about Exjade. In this Myfortic phase of the case, Novartis has argued that there were in fact no side agreements with Myfortic specialty pharmacies to promote or convert in exchange for discounts and rebates. In this phase, Novartis did not choose to present evidence regarding the advice of its attorneys.

Because a party has no obligation to disclose its privileged communications with its attorneys, you must not attach any significance to the fact that Novartis did not present evidence regarding the advice of its attorneys with respect to Myfortic. No adverse inference against Novartis may be drawn by you because it did not present testimony or evidence about the advice of its attorneys, and you may not consider it in any way in your deliberations in the jury room.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Criminal, Instruction 5-21 (Lexis 2015) (“The defendant chose not to testify in this case. Under our Constitution, a defendant has no obligation to testify or to present any evidence, because it is the Government’s burden to prove a defendant guilty beyond a reasonable doubt. A defendant is never required to prove that he or she is innocent. Therefore, you must not attach any significance to the fact that a given defendant did not testify. No adverse inference against a defendant may be drawn by you because he or she did not take the witness stand, and you may not consider it in any way in your deliberations in the jury room.”); Upjohn Co. v. United States, 449 U.S. 383, 389

(1981) (The attorney-client privilege’s “purpose is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice.”).

### **III. GOVERNING LAW**

#### **Jury Instruction No. 24: False Claims Act and Anti-Kickback Statute**

As I explained when I began these instructions, this case involves the False Claims Act. In general, the False Claims Act prohibits a person or company from causing the submission of false or fraudulent claims to the government in connection with a request for payment.

Plaintiffs in this case allege that specialty pharmacies submitted claims that were false or fraudulent because of violations of a separate statute called the Anti-Kickback Statute. I will call the Anti-Kickback Statute the AKS. If a specialty pharmacy violates the AKS but certifies that it is in compliance with the AKS, the claim it submits may be false or fraudulent. On the other hand, if there is no violation of the AKS, the claim is not false or fraudulent.

Plaintiffs allege that Novartis caused the specialty pharmacies to submit false claims. In order to cause the submission of false claims, an entity must knowingly commit a fraudulent act. Plaintiffs contend that Novartis's violation of the AKS was the fraudulent act that caused the specialty pharmacies to submit a false claim. Thus, in addition to considering whether the specialty pharmacies violated the AKS, you must determine whether Novartis violated the AKS. If you find that Novartis did not violate the AKS, then you must find that Novartis did not knowingly cause a false claim or statement to be submitted.

Because your resolution of Plaintiffs' False Claims Act allegations will involve determining whether there were violations of the AKS, I will now explain the elements of the AKS before turning back to the requirements of the False Claims Act.

AUTHORITY: Mem. and Order Denying in Part Mot. to Dismiss at 19, Aug. 7, 2014, ECF No. 227 (“[T]he Government has sufficiently pleaded that many of the Myfortic and Exjade claims submitted by the pharmacies were rendered legally ‘false’ by the pharmacies’ false certifications of compliance with the AKS.”); see also Mem. and Order Denying in Part Mot. to Dismiss at 4, Sept. 4, 2014, ECF No. 234 (“In this case, the Intervening States’ claims are predicated on underlying violations of the Anti-Kickback Statutes (‘AKS’) and its state law parallels.”); Mem. and Order Denying in Part Mot. to Dismiss at 3, Sept. 3, 2014, ECF No. 233 (“In this case, the Relator’s FCA claims are predicated on underlying violations of the Anti-Kickback Statute”).

**Jury Instruction No. 25: Elements of the Anti-Kickback Statute**

Plaintiffs claim that Novartis and the specialty pharmacies violated the AKS. The AKS prohibits:

“knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase or . . . recommend purchasing . . . or ordering any [drug] for which payment may be made in whole or in part under a Federal health care program.”

Another relevant portion of the AKS prohibits:

“knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for . . . recommending purchasing . . . or [recommending] ordering any [drug] for which payment may be made in whole or in part under a Federal health care program.”

In this case, to show that Novartis and a specialty pharmacy violated the AKS, Plaintiffs must prove by a preponderance of the evidence all of the following four elements, each of which I will explain in greater detail:

First, that Novartis offered or paid remuneration and that the specialty pharmacy solicited or received remuneration;

Second, that Novartis made the offer or payment of remuneration to induce a specialty pharmacy to recommend purchasing or ordering [Exjade/Myfortic] and that the specialty pharmacy’s solicitation or receipt of remuneration was in return for that specialty pharmacy’s recommending purchasing or recommending ordering [Exjade/Myfortic];

Third, that [Exjade/Myfortic] was or could have been paid for in whole or in part by a government health care program, such as Medicare or Medicaid; and

Fourth, that Novartis and the specialty pharmacy acted knowingly and willfully.

You should assess the evidence separately as to Novartis and each pharmacy at issue.

AUTHORITY: Adapted from Charge of Hon. Sandra Townes, Trial Tr. 1279:13-1280:2, 1286:6-19, United States v. Krikheli, No. 08-CR-528 (E.D.N.Y. Mar. 4, 2009) (Ex. 6) (ECF No. 231), aff'd 461 F. App'x 7 (2d Cir. 2012) (finding another aspect of the charge proper); 42 U.S.C. § 1320a-7b(b)(1)(B), (2)(B).

**Jury Instruction No. 26:**     **First Element—Definition of Remuneration**

Let me now discuss each element of the AKS in more detail. You will recall that the first element Plaintiffs must prove by a preponderance of the evidence is that Novartis offered or paid remuneration and that a specialty pharmacy solicited or received remuneration.

The term “remuneration” means the transfer of anything of value from one person or entity to another person or entity. The statute specifies that the term “remuneration” includes kickbacks, bribes and rebates. The term “kickback” means the return of a portion of a payment after the time of the sale. The term “bribe” means the corrupt transfer of anything of value from one person or entity to another person or entity to accomplish some unlawful result or to accomplish some lawful result by some unlawful means. A rebate is a type of discount where a portion of the payment is returned to a buyer after the time of the sale.

As I will explain later, not all rebates are prohibited by the AKS.

AUTHORITY: Adapted from Charge of Hon. Sandra Townes, Trial Tr. 1280:3-20, United States v. Krikheli, No. 08-CR-528 (E.D.N.Y. Mar. 4, 2009) (Ex. 6) (ECF No. 231), aff’d 461 F. App’x 7, 11 (2d Cir. 2012) (finding charge proper).

**Jury Instruction No. 27: First Element—Definition of Offer and Solicit**

The word “offer” means a representation expressing the ability and desire to pay a remuneration coupled with the intent to induce a desired action. The word “solicit” means to ask for something in a persuasive and determined way.

AUTHORITY: Court’s Jury Instructions, United States v. Robinson, No. H-09-422, 2011 WL 885843 (S.D. Tex Mar. 7, 2011) (ECF No. 260 at Tr. 704:18-21), aff’d, 505 F. App’x 385 (5th Cir. 2013); see United States v. Duz-Mor Diagnostic Lab., Inc., 650 F.2d 223, 227 (9th Cir. 1981) (citing United States v. Jacobs, 431 F.2d 754, 759 (2nd Cir. 1970)); “Solicit”, Cambridge American English Dictionary, <http://dictionary.cambridge.org/us/dictionary/american-english/solicit> (last visited June 26, 2015).

**Jury Instruction No. 28:      Second Element—Purpose of Remuneration**

The second element of the AKS that Plaintiffs must prove by a preponderance of the evidence is that any offer or payment that Novartis made and that the specialty pharmacy solicited or received was for the purpose of inducing the specialty pharmacy to recommend purchasing or ordering [Exjade/Myfortic].

AUTHORITY: Adapted from Charge of Hon. Sandra Townes, Trial Tr. 1280:21-1281:1, 1287:10-15, United States v. Krikheli, No. 08-CR-528 (E.D.N.Y. Mar. 4, 2009) (Ex. 6) (ECF No. 231), aff'd 461 F. App'x 7, 11 (2d Cir. 2012) (finding charge proper).

**Jury Instruction No. 29:**     **Second Element—Meaning of “to induce” and “in return for”**

To offer or pay remuneration to induce recommendations means to offer or pay remuneration with intent to gain influence over the reason or judgment of a person making decisions to recommend. The intent to gain such influence must, at least in part, have been the reason the remuneration was offered or paid.

On the other hand, Novartis did not violate the AKS merely because it hoped or expected or believed that recommendations by the pharmacies may follow from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to recommend [Exjade/Myfortic] does not violate the law. There must be an offer or payment of remuneration to induce recommendations, as I have just defined it.

Likewise, in order to sustain its burden of proof regarding the specialty pharmacies’ alleged violations of the AKS, Plaintiffs must prove that the specialty pharmacy under consideration solicited or received the remuneration with the intent that the remuneration be “in return for” recommendations. To solicit or receive remuneration in return for recommendations means to solicit or receive remuneration with intent to allow the remuneration to influence the reason and judgment behind one’s recommendation decisions. The intent to be influenced in one’s recommendations must, at least in part, have been the reason the remuneration was solicited or received.

On the other hand, you cannot find that specialty pharmacies violated the AKS merely because they received remuneration wholly in return for services and also made the decision to recommend [Exjade/Myfortic]. Likewise, mere recommendation of [Exjade/Myfortic] because of oral encouragement or because of a belief that the drug

benefits patients does not violate the law. There must be a solicitation or receipt of remuneration in return for recommendations, as I have just defined it.

AUTHORITY: Adapted from United States v. LaHue, 261 F.3d 993, 1003 & nn. 10-11 (10th Cir. 2001) (affirming the use of two instructions that have been adapted to the facts of this case).

**Jury Instruction No. 30: Second Element—Quid Pro Quo**

In order to make out this second element of the AKS, Plaintiffs must prove by a preponderance of the evidence that Novartis offered or paid the remuneration as a quid pro quo in return for the specialty pharmacies recommending purchasing or ordering [Exjade/Myfortic].

In addition, in order to make out this second element of the AKS, Plaintiffs must prove by a preponderance of the evidence that a specialty pharmacy solicited or received remuneration as a quid pro quo in return for the specialty pharmacy recommending purchasing or ordering [Exjade/Myfortic].

“Quid pro quo” is a Latin phrase that means a direct exchange of one thing for another. In this case, it means Plaintiffs must prove that Novartis offered or paid remuneration as a direct exchange for pharmacies’ making recommendations of [Exjade/Myfortic] and that the specialty pharmacies solicited or received remuneration from Novartis as a direct exchange for making recommendations of [Exjade/Myfortic].

AUTHORITY: Adapted from Charge of Hon. Sandra Townes, Trial Tr. 1281:2-14, United States v. Krikheli, No. 08-CR-528 (E.D.N.Y. Mar. 4, 2009) (Ex. 6) (ECF No. 231), aff’d 461 F. App’x 7, 11 (2d Cir. 2012) (The “prosecution had to prove ‘that the remuneration was offered or paid as a quid pro quo in return for the referring of the patient.’ These instructions accurately described the law . . . . [T]he instructions made clear that the government was required to prove that any payments to middlemen were made to induce referrals in a quid pro quo transaction.”) (internal citation omitted).

**Jury Instruction No. 31:**     **Second Element—Meaning of recommendation**

To “recommend purchasing or ordering” [Exjade/Myfortic] means to propose or to establish a plan of care that includes purchasing or ordering [Exjade/Myfortic]. To prove the second element of the AKS, Plaintiffs must prove by a preponderance of the evidence that Novartis made an offer or payment of remuneration to induce specialty pharmacies either to propose or to establish a plan of care for the patients to whom they delivered [Exjade/Myfortic].

AUTHORITY: Stark Act, 42 U.S.C. § 1395nn(h)(5)(B) (2012) (“[T]he request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a ‘referral’”); see United States v. Patel, 778 F.3d 607, 614 & n.4, 615 (7th Cir. 2015) (relying upon the definition of “referral” in the Stark Act, a “related federal statute”, to interpret the AKS and holding that “refer” and “recommend” as used in the AKS are synonymous).

**Jury Instruction No. 32:**      **Second Element—Statutory Exception and Regulatory Safe Harbor**

As I mentioned earlier, not all discounts or rebates are prohibited by the AKS. A discount is a reduction in the amount a buyer is charged for an item or service based on an arm's-length transaction. A rebate is a type of discount in which a portion of the purchase price is returned to a buyer after the time of the sale.

Novartis has argued that certain payments to specialty pharmacies were lawful discounts or rebates. The burden is on Plaintiffs to prove by a preponderance of the evidence that these payments were not lawful. To show that a discount or rebate violated the AKS, Plaintiffs must prove by a preponderance of the evidence the following two things.

First, Plaintiffs must prove by a preponderance of the evidence that the amount of the discount or rebate was not properly disclosed or appropriately reflected in the claims the specialty pharmacies made to Medicare or Medicaid. If Plaintiffs do not meet that burden, you must find that any discount or rebate in price did not violate the AKS.

Second, Plaintiffs must also prove that Novartis did not inform the specialty pharmacies of their obligations to report the discount or rebate to the government or that Novartis did something to impede the specialty pharmacies' ability to meet their obligations. In the case of a rebate, Plaintiffs may instead show that the terms of the rebate were not fixed or disclosed in writing to the specialty pharmacies at the time of the purchase to which the rebate applies. If Plaintiffs do not meet this burden, you must find that any such discount, rebate or other reduction in price did not violate the AKS.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Criminal, Instruction 27A-30 (Lexis 2015); see 42 U.S.C. § 1320a-7b(b)(3)(A) (The AKS does not apply to “a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program”.); 42 C.F.R. § 1001.952(h)(3)(iii) (excepting a discount from the definition of “remuneration” in the AKS so long as the offeror of a discount complies with the applicable standards of paragraph (h)(3): “[iii)(A)] The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section. [(iii)(B)] The offeror of the discount must refrain from doing anything that would impede the buyer’s or seller’s ability to meet its obligations under this paragraph.”); id. § 1001.952(h)(4) (“For the purposes of this paragraph, a rebate is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.”).

**Jury Instruction No. 33: Third Element—Coverage by Health Care Program**

The third element is that the prescriptions or refills of [Exjade/Myfortic] were or could have been paid for in whole or in part by Plaintiffs' health care programs.

A "Plaintiff health care program" is any plan or program that provides health benefits and that is funded, either directly or indirectly, by one or more of the Plaintiff governments.

Medicare or Medicaid are examples of a "plaintiff health care program."

AUTHORITY: Adapted from Charge of Hon. Sandra Townes, Trial Tr. 1281:15-1282:4, United States v. Krikheli, No. 08-CR-528 (E.D.N.Y. Mar. 4, 2009) (Ex. 6) (ECF No. 231), aff'd 461 F. App'x 7, 10-11 (2d Cir. 2012) (finding another aspect of this charge proper).

**Jury Instruction No. 34: Fourth Element—Acting Knowingly and Willfully**

The fourth element that Plaintiffs must prove by a preponderance of the evidence is that Novartis and the specialty pharmacies acted both knowingly and willfully.

A person acts knowingly if he or she acts voluntarily and with an awareness of what he or she is doing, not because of ignorance, mistake or accident. A person does not act knowingly simply because a reasonable person in the person's position should have been strongly suspicious, or should have been aware of unlawful activity.

A person acts willfully when he or she acts with knowledge that his or her conduct is unlawful and with intent to do something that the law forbids—that is, with the bad purpose to disobey or disregard the law. A person acts willfully if he or she acts unjustifiably and wrongly while knowing that his or her actions are unjustifiable and wrong. A person's conduct is not willful if you find that it was due to negligence, inadvertence, misunderstanding or mistake.

Here, if you find that Novartis did not knowingly and willfully offer or pay remuneration in order to induce specialty pharmacies to recommend [Exjade/Myfortic], then you must find that Novartis did not violate the AKS. If you find that the specialty pharmacies did not knowingly and willfully solicit or accept remuneration in return for recommending [Exjade/Myfortic], then you must find that the specialty pharmacies did not violate the AKS.

AUTHORITY: Adapted from Charge of Hon. Sandra Townes, Trial Tr. 1282:5-18, United States v. Krikheli, No. 08-CR-528 (E.D.N.Y. Mar. 4, 2009) (Ex. 6) (ECF No. 231), aff'd 461 F. App'x 7 (2d Cir. 2012); Klaczak v. Consol. Med. Transp., 458 F.

Supp. 2d 622, 674 (N.D. Ill. 2006); Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Criminal, Instruction 27A-31 (Lexis 2015).

**Jury Instruction No. 35:      Fourth Element—Good Faith**

If Novartis or the specialty pharmacies acted in good faith, then they lacked the willfulness required to prove a violation of the AKS. If Novartis or the specialty pharmacies believed in good faith that they were acting properly, even if they were mistaken in that belief, there is no violation of the AKS.

[Exjade phase only: You have heard evidence that Novartis relied on the advice of its attorneys regarding the lawfulness of the activities challenged in this litigation. Such evidence is relevant to determining whether Novartis lacked the knowledge and willfulness required to prove a violation of the AKS.]

The burden of proving that Novartis and the specialty pharmacies acted knowingly and willfully is on the Plaintiffs. Novartis has no burden to prove that it or the specialty pharmacies acted in good faith; rather, Plaintiffs must prove by a preponderance of the evidence that Novartis and the specialty pharmacies acted in bad faith or with knowledge of the unlawfulness of their conduct.

AUTHORITY: Adapted from Hon. Leonard B. Sand et al., Modern Federal Jury Instructions—Criminal, Instruction 8-1 (Lexis 2015); Seventh Circuit Federal Jury Instructions—Criminal, Instruction 6.10 (West 2012).

**Jury Instruction No. 36: Elements of (a)(1)(A) Violation**

I will now turn back to the False Claims Act. In relevant part, the False Claims Act makes liable anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or anyone who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” or anyone who “conspires to commit a violation of [the False Claims Act].”

Plaintiffs have alleged three types of violations under the False Claims Act. Under the first type of violation alleged, Plaintiffs must establish by a preponderance of the evidence that:

- (1) there was a false or fraudulent claim;
- (2) Novartis knew the claim was false or fraudulent;
- (3) Novartis knowingly caused the claim to be presented to one or more of Plaintiffs for payment;
- (4) the false or fraudulent claim was material to Plaintiffs’ decisions to pay; and
- (5) Plaintiffs suffered damages as a result of the false or fraudulent claim.

AUTHORITY: Adapted from Final Jury Instructions at 5-6, United States v. J-M Mfg. Co., No. EDCV 06-55 (C.D. Cal. Nov. 14, 2013) (Ex. 7) (ECF No. 1792); 31 U.S.C. § 3729(a)(1)(A)-(C); U.S. ex rel. Kester v. Novartis Pharms. Corp. (Novartis IV), 41 F. Supp. 3d 323, 328 (S.D.N.Y. 2014) (citing Mikes v. Straus, 274 F.3d 687, 695 (2d Cir. 2001)); 31 U.S.C. § 3731(d) (“In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.”); U.S. ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 432 (S.D.N.Y. 1999) (McMahon, J.) (“To prevail on a claim under § 3729(a)(1), a relator must establish . . . (4) the United States suffered damages as a result of the false

or fraudulent claim. Similarly, a plaintiff bringing a claim under § 3729(a)(2) must show that . . . (4) the United States suffered damages as a result of the false or fraudulent claim. Finally, to satisfy the elements of a conspiracy to defraud claim under § 3729(a)(3), a plaintiff is required to demonstrate that . . . (3) the United States has suffered damages as a result of the false or fraudulent claim. . . . I find [the rule that damages is a required element] to be the more persuasive position.”) (citations omitted)); Veridyne Corp. v. United States, 758 F.3d 1371, 1378 (Fed. Cir. 2014) (“To recover under the FCA, the Government must show . . . (4) the United States suffered damages as a result of the false or fraudulent claim.”) (citation omitted); Ulysses, Inc. v. United States, 110 Fed. Cl. 618, 641 (2013) (“To establish that a plaintiff is liable under the False Claims Act, the Government must show that . . . (4) the Government suffered damages because of the false or fraudulent claim.”).

**Jury Instruction No. 37: Elements of (a)(1)(B) Violation**

Under the second type of violation alleged, Plaintiffs must establish by a preponderance of the evidence that:

- (1) there was a false statement;
- (2) Novartis knew the statement was false;
- (3) Novartis knowingly caused the false statement to be made or used;
- (4) the statement was material to a false or fraudulent claim; and
- (5) Plaintiffs suffered damages as a result of the false or fraudulent

claim.

AUTHORITY: Adapted from Final Jury Instructions at 5-6, United States v. J-M Mfg. Co., No. EDCV 06-55 (C.D. Cal. Nov. 14, 2013) (Ex. 7) (ECF No. 1792); 31 U.S.C. § 3729(a)(1)(B); U.S. ex rel. Kester v. Novartis Pharms. Corp. (Novartis IV), 41 F. Supp. 3d 323, 328 (S.D.N.Y. 2014); 31 U.S.C. § 3731(d) (“In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.”); U.S. ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 432 (S.D.N.Y. 1999) (McMahon, J.) (“To prevail on a claim under § 3729(a)(1), a relator must establish . . . the United States suffered damages as a result of the false or fraudulent claim. Similarly, a plaintiff bringing a claim under § 3729(a)(2) must show that . . . the United States suffered damages as a result of the false or fraudulent claim.” (citations omitted)); Veridyne Corp. v. United States, 758 F.3d 1371, 1378 (Fed. Cir. 2014); Ulysses, Inc. v. United States, 110 Fed. Cl. 618, 641 (2013).

**Jury Instruction No. 38: Summary of (a)(1)(A) and (a)(1)(B) Violations**

In this case, you will be asked to decide as to each Plaintiff:

- (1) First, was there a false or fraudulent claim or statement?
- (2) Second, did Novartis know that the claim or statement was false?
- (3) Third, did Novartis knowingly cause the false or fraudulent claim or statement to be submitted to the Plaintiff?
- (4) Fourth, was the false or fraudulent claim or false statement “material,” as I will define, to the Plaintiff?
- (5) Fifth, did Plaintiffs suffer damages as a result of the false or fraudulent claim?

I will explain the first four elements now, and the fifth element of damages at the end of these instructions.

AUTHORITY: Adapted from Final Jury Instructions at 5-6, United States v. J-M Mfg. Co., No. EDCV 06-55 (C.D. Cal. Nov. 14, 2013) (Ex. 7) (ECF No. 1792).

**Jury Instruction No. 39:**     **First Element of FCA—Falsity**

The first element of both types of violations is that there was a false or fraudulent claim or statement. A claim is false if it is an assertion that is untrue when made or when used. A claim is fraudulent if it is an assertion that is known to be untrue. A statement that a person will comply with a law in the future is not false or fraudulent unless at the time the statement was made the person intended not to comply with the law or knew that he or she could not comply with the law in the future.

AUTHORITY: Adapted from Charge of Hon. William H. Pauley III, Trial Tr. 1468:22-1469:7, U.S. ex rel. Feldman v. van Gorp, No. 03-Civ.-8135 (S.D.N.Y. July 22, 2010) (Ex. 1), aff'd 697 F.3d 78 (2d Cir. 2012).

**Jury Instruction No. 40: First Element—Connection Between AKS and Falsity**

In this case, Plaintiffs allege that certain claims or statements submitted by the specialty pharmacies to Medicare and Medicaid for reimbursement were false because the specialty pharmacies were violating the AKS while they were certifying compliance with the AKS.

Plaintiffs must therefore prove by a preponderance of the evidence that the specialty pharmacies violated the AKS. If Plaintiffs fail to prove that the specialty pharmacies violated the AKS, you must find for Novartis on this element.

In addition, Plaintiffs must prove by a preponderance of the evidence that the specialty pharmacies submitted false certifications that they were in compliance with the AKS. If Plaintiffs fail to prove that the specialty pharmacies submitted false certifications, then you must find for Novartis on this element. This requirement that Plaintiffs prove that the pharmacies certified compliance with the AKS only applies to the period before March 23, 2010.

AUTHORITY: U.S. ex rel. Kester v. Novartis Pharms. Corp. (Novartis IV), 41 F. Supp. 3d 323, 328-35 (S.D.N.Y. 2014).

**Jury Instruction No. 41:**     **First Element—Connection Between AKS and Falsity—Causation**

Only a claim that includes items that were purchased as a result of a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. That means that Plaintiffs must prove that the alleged kickback scheme caused claims to be made that would not have been made had it not been for the kickback scheme.

AUTHORITY: 42 U.S.C. § 1320a-7b(g) (“A claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim”); U.S. ex rel. Chen v. EMSL Analytical, Inc., No. 10-7504, 2013 WL 4441509, at \*18 (S.D.N.Y. Aug. 16, 2013) (dismissing FCA claims because the “precise manner in which Defendants’ ‘fake’ samples and ‘false’ testing reports are linked to the ‘false reports and invoices’ allegedly submitted to the government remains unclear”) (emphasis added); U.S. ex rel. Mooney v. Americare, Inc., No. 06-1806, 2013 WL 1346022, at \*3-\*4 (E.D.N.Y. Apr. 3, 2013) (dismissing FCA claims because details about the fraudulent kickback scheme were “unconnected to specific claims”); U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 35 (D.D.C. 2003) (dismissing FCA claims because the complaint alleged a kickback scheme but did not “link [the] scheme to claims for payment made to the United States”).

**Jury Instruction No. 42:     Second Element—Overview of Knowledge**

The second element that Plaintiffs must prove by a preponderance of the evidence is that Novartis knew that the claim or statement was false or fraudulent. In this case, Plaintiffs must show that Novartis knew that the specialty pharmacies were falsely certifying compliance with the AKS.

AUTHORITY: Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1057-59 (11th Cir. 2015).

**Jury Instruction No. 43: Second Element—Corporate Knowledge**

Novartis is a corporation. Plaintiffs cannot prove that Novartis acted knowingly by piecing together scraps of knowledge from all the employees in the corporation. In order to find that Novartis took any action knowingly, you must find that at least one employee had all of the relevant factual information to satisfy the “knowledge” standard under the False Claims Act. In this particular case, that means that you would need to find that at least one employee with authority to act on behalf of Novartis knew that Novartis was causing specialty pharmacies to submit claims to Medicare or Medicaid and knew that those claims were false.

AUTHORITY: Adapted from Jury Instructions at 12-13, U.S. ex rel. Drakeford v. Tuomey, C/A No. 05-2858 (D.S.C. May 8, 2013) (Ex. 8) (ECF No. 810); see United States v. Sci. Applications Int’l Corp., 626 F.3d 1257, 1274-77 (D.C. Cir. 2010) (vacating district court’s judgment for giving the jury a “collective knowledge” instruction); United States v. United Techs. Corp., 51 F. Supp. 2d 167, 196-99 (D. Conn. 1999) (declining to apply the collective knowledge doctrine); U.S. ex rel. Dyer v. Raytheon Co., No. Civ. 08-10341, 2013 WL 5348571, at \*26 (D. Mass. Sept. 23, 2013) (citing United Techs.) (“[Relator] Dyer must show that a single individual, acting on behalf of Raytheon had the requisite knowledge and approved the false claims”); see also Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 195 (2d Cir. 2008) (“To prove liability against a corporation, of course, a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to the corporation.”) (emphasis added).

**Jury Instruction No. 44:**     **Second Element—Knowledge of Falsity**

In order to prove that Novartis knew the claims or statements were false, Plaintiffs must prove by a preponderance of the evidence that Novartis either actually knew that the specialty pharmacies' certifications of compliance with the AKS were false or acted in deliberate ignorance or reckless disregard of whether the certifications of compliance with the AKS were false.

AUTHORITY: Adapted from 31 U.S.C. § 3729(b)(1).

**Jury Instruction No. 45: Second Element—Reasonable Interpretation**

When I say that Plaintiffs must show that Novartis “knowingly” caused a false or fraudulent claim or statement to be submitted, I do not mean that the claim was technically inaccurate or incorrect as a matter of proper legal analysis. Rather, I mean that the claim or statement was a lie. In a case where the truth or falsity of a statement centers on an interpretive question of law, Plaintiffs bear the burden of proving by a preponderance of the evidence that the challenged statement is not true under any reasonable interpretation of the law.

AUTHORITY: U.S. ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 438 (S.D.N.Y. 1999) (McMahon, J.) (“The phrase ‘known to be false’ in section 3729 does not mean ‘scientifically untrue’; it means ‘a lie.’”) (alterations and citations omitted), aff’d 274 F.3d 687, 703 (2d Cir. 2001) (“The notion of presenting a claim known to be false does not mean the claim is incorrect as a matter of proper accounting, but rather means it is a lie.”) (citing Hagood v. Sonoma Cnty. Water Agency, 81 F.3d 1465, 1478 (9th Cir. 1996)); U.S. ex rel. Finney v. Nextwave Telecom, Inc., 337 B.R. 479, 488 (S.D.N.Y. 2006) (McMahon, J.) (“[U]nresolved disputes about the proper interpretation of a statute or regulation should not lead to suits under the FCA, at least where a claimant’s interpretation of the governing law is reasonable.” (internal quotation marks omitted)); United States v. Whiteside, 285 F.3d 1345, 1351 (11th Cir. 2002) (collecting cases) (“In a case where the truth or falsity of a statement centers on an interpretive question of law, the government bears the burden of proving beyond a reasonable doubt that the defendant’s statement is not true under a reasonable interpretation of the law.”); Hagood v. Sonoma Cnty. Water Agency, 81 F.3d 1465, 1477 (9th Cir. 1996) (“Even viewing Hagood’s evidence in the most favorable light, that evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was false within the meaning of the False Claims Act.”)

**Jury Instruction No. 46: Second Element—Actual Knowledge**

Plaintiffs may prove Novartis acted knowingly by proving, by a preponderance of the evidence, that Novartis had actual knowledge that the AKS was being violated and that specialty pharmacies were certifying compliance with the AKS. It means that Novartis actually realized there was a violation of the AKS and did not act through ignorance, mistake, or accident.

AUTHORITY: Adapted from Jury Instructions at 12, U.S. ex rel. Drakeford v. Tuomey, C/A No. 05-2858 (D.S.C. May 8, 2013) (Ex. 8) (ECF No. 810).

**Jury Instruction No. 47:**     **Second Element—Deliberate Ignorance and Reckless Disregard**

Plaintiffs may also prove that Novartis acted “knowingly” by proving that Novartis acted with deliberate ignorance or reckless disregard for whether the specialty pharmacies’ certifications of compliance with the AKS were false. Deliberate ignorance or reckless disregard means that a defendant had reason to believe that claims or statements contained inaccurate information, but failed to make an investigation into whether or not the information submitted to the government was true. This standard is meant to target a defendant who has “buried his head in the sand” and failed to make some limited inquiry into a claim’s validity. However, there is no duty to make a burdensome inquiry.

In order to prove deliberate ignorance or reckless disregard, Plaintiffs must prove by a preponderance of the evidence that Novartis had reason to believe that the pharmacy claims contained inaccurate information and, if so, failed to make such an investigation as would be reasonable and prudent to conduct under the circumstances. On the other hand, if you find that Novartis had no reason to believe that pharmacy claims contained inaccurate information, or if you find that Novartis did conduct a reasonable and prudent investigation into whether or not there was a violation of the AKS, then you cannot find Novartis liable.

[Exjade phase only: You have heard evidence that Novartis relied on the advice of its attorneys regarding the lawfulness of the activities challenged in this litigation. Such evidence is relevant to determining whether Novartis conducted a reasonable and prudent investigation into whether or not there was a violation of the AKS.]

AUTHORITY: S. Rep. No. 99-345, at 20-21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5285-86; U.S. ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 438-39 (S.D.N.Y. 1999) (McMahon, J.) (citing S. Rep. No. 99-345), aff'd 274 F.3d 687 (2d Cir. 2001); Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1058 & n.15 (11th Cir. 2015); U.S. ex rel. Williams v. Renal Care Grp., Inc., 696 F.3d 518, 530-31 (6th Cir. 2012).

**Jury Instruction No. 48: Third Element—Caused Claim to be Made**

The third element that Plaintiffs must prove by a preponderance of the evidence is that Novartis caused the false or fraudulent claims or statements to be made to Plaintiffs. In order to find that Novartis's conduct caused false claims or statements to be submitted, you must determine that its conduct was a substantial factor in producing the harm and that the outcome was foreseeable.

Thus, in evaluating causation in this case, it is the knowledge and conduct of Novartis that matters and not of the actual submitter of the claims, here, the specialty pharmacies. If Novartis did not knowingly act or did not commit a fraudulent act, then you must find that Novartis did not knowingly cause a false claim or statement to be submitted.

AUTHORITY: Adapted from Jury Instruction No. 31 at 37, U.S. ex rel. Bunk v. Gosselin Worldwide Moving N.V., No. 1:02-cv-01168, (E.D. Va. Aug. 1, 2014) (Ex. 2) (ECF No. 1312-3).

**Jury Instruction No. 49:     Fourth Element—Materiality**

The fourth element Plaintiffs must prove by a preponderance of the evidence is that the false or fraudulent claim or statement was material to the government Plaintiffs' decisions to pay. A material statement is a statement that has a natural tendency to influence government funding decisions or is capable of influencing those decisions.

AUTHORITY: Charge of Hon. William H. Pauley III, Trial Tr. 1471:1-7, U.S. ex rel. Feldman v. Van Gorp, No. 03-cv-8135 (S.D.N.Y. July 22, 2010) (Ex. 1), aff'd 697 F.3d 78 (2d Cir. 2012).

**Jury Instruction No. 50:**     **Fifth Element—Damages**

The fifth element that Plaintiffs must prove by a preponderance of the evidence is that they suffered damages because of the acts of Novartis. As I mentioned before, I will explain this element in depth at the end of these instructions.

For now, I instruct you that Plaintiffs have proven that they suffered damages only if they can demonstrate, by a preponderance of the evidence, that they lost money as a result of the alleged kickback scheme.

AUTHORITY: 31 U.S.C. § 3731(d) (“In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.”); U.S. ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 432 (S.D.N.Y. 1999) (McMahon, J.).

**Jury Instruction No. 51: Elements of (a)(1)(C) Violation**

Finally, I will tell you about a third type of False Claims Act violation that Plaintiffs have alleged. Under this third type of violation, Plaintiffs must establish by a preponderance of the evidence that:

- (1) Novartis entered into an unlawful agreement with a specialty pharmacy to violate the False Claims Act;
- (2) Before May 20, 2009, Novartis and its coconspirators shared the specific intent to defraud the government, or that after May 20, 2009, Novartis and its coconspirators shared the intent to commit a violation of the False Claims Act;
- (3) At least one member of the conspiracy violated the False Claims Act; and
- (4) Plaintiffs suffered damages as a result of the false or fraudulent claim.

If Plaintiffs fail to prove a violation of the Act, then you must find there was no conspiracy. I will explain the first three elements now, and the fourth element of damages at the end of these instructions.

AUTHORITY: U.S. ex rel. Kester v. Novartis Pharms. Corp. (Novartis IV), 41 F. Supp. 3d 323, 328 (S.D.N.Y. 2014) (citing Mikes v. Straus, 274 F.3d 687, 695 (2d Cir. 2001)); U.S. ex rel. Wuestenhoefer v. Jefferson, No. 4:10-CV-00012, 2015 WL 226026, at \*25 (N.D. Miss. Jan. 16, 2015); United States ex rel. Rockey v. Ear Inst. of Chicago, LLC, No. 11 C 7258, 2015 WL 1502378, at \*14 (N.D. Ill. Mar. 25, 2015); U.S. ex rel. Petras v. Sampirel, Inc., No. CIV.A. 13-2415 FLW, 2015 WL 337472, at \*8 (D.N.J. Jan. 26, 2015); Pencheng Si v. Laogai Research Found., No. 09-CV-2388, 2014 WL 5446487, at \*10 (D.D.C. Oct. 14, 2014); 31 U.S.C. § 3731(d); U.S. ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 432 (S.D.N.Y. 1999) (McMahon, J.); see also Veridyne Corp. v. United States, 758 F.3d 1371, 1378 (Fed. Cir. 2014); Ulysses, Inc. v. United States, 110 Fed. Cl. 618, 641 (2013).

**Jury Instruction No. 52: First Element—Unlawful Agreement**

A conspiracy is an agreement between two or more persons or corporations to injure another by unlawful action.

To find a conspiracy between Novartis and any particular specialty pharmacy to violate the False Claims Act, you must believe that there was an unlawful agreement between Novartis and that specialty pharmacy to get a false or fraudulent claim allowed or paid.

The essence of a conspiracy is an agreement between two or more persons to commit fraud. Plaintiffs must demonstrate a meeting of the minds to accomplish an unlawful purpose. To establish a meeting of the minds, it is not sufficient for Plaintiffs to provide proof that the alleged conspirators intended to engage in the conduct that resulted in the injury. Instead, Novartis and the specialty pharmacies had to be aware of the harm or wrongful conduct to be committed at the inception of the agreement.

AUTHORITY: Adapted from Court's Instructions to the Jury at 14, U.S. ex rel. Gonzalez v. Fresenius Med. Care N. Am., No. 07-CV-247 (W.D. Tex. Feb. 25, 2010) (Ex. 9) (ECF No. 451), aff'd 689 F.3d 470 (5th Cir. 2012); see U.S. ex rel. Westmoreland v. Amgen Inc., 738 F. Supp. 2d 267, 272, 280 (D. Mass. 2010) (citing U.S. ex rel. Gagne v. City of Worcester, 565 F.3d 40, 46 (1st Cir. 2009)); U.S. ex rel. Atkinson v. Pa. Shipbuilding Co., No. Civ. A. 94-7316, 2004 WL 1686958, at \*4 (E.D. Pa. July 28, 2004), aff'd on other grounds, 473 F.3d 506 (3d Cir. 2007).

**Jury Instruction No. 53:**     **First Element—Business Arrangements Are Not  
Themselves Evidence of a Conspiracy**

The mere fact that Novartis had business arrangements or other arrangements with the specialty pharmacies is not evidence of a conspiracy. Rather, the only agreement that can support a conspiracy in this case is if you find by a preponderance of the evidence that there was an agreement to violate the False Claims Act.

AUTHORITY: See Transcript of Jury Trial at 1788:5-17, 1791:7-13, U.S. ex rel. Rigsby v. State Farm, No 1:06CV433 (S.D. Miss. Apr. 5, 2013) (Ex. 10) (ECF No. 1124).

**Jury Instruction No. 54: Second Element—Specific Intent to Defraud**

For conduct occurring before May 20, 2009, Plaintiffs must also prove by a preponderance of the evidence that the members of the conspiracy had a specific intent to defraud the government. To find for Plaintiffs on this element, it is not enough that Novartis had knowledge of the false statement or claim, or that it was reckless as to the falsity of the statement or claim. Instead, Novartis must have actually intended to get a false or fraudulent claim allowed or paid.

AUTHORITY: Allison Engine Co., Inc. v. U.S. ex rel. Sanders, 553 U.S. 662, 672 (2008); U.S. ex rel. Wuestenhoefer v. Jefferson, No. 4:10-CV-00012, 2015 WL 226026, at \*25 (N.D. Miss. Jan. 16, 2015); Transcript of Jury Trial at 1788:5-17, U.S. ex rel. Rigsby v. State Farm, No 1:06CV433 (S.D. Miss. Apr. 5, 2013) (Ex. 10) (ECF No. 1124).

**Jury Instruction No. 55:**     **Third Element—Violation of FCA**

Plaintiffs must prove by a preponderance of the evidence that at least one member of the conspiracy actually violated the False Claims Act. If Plaintiffs fail to prove a violation of the Act, then you must find there was no conspiracy.

AUTHORITY: U.S. ex rel. Rockey v. Ear Inst. of Chicago, LLC, No. 11 C 7258, 2015 WL 1502378, at \*14 (N.D. Ill. Mar. 25, 2015) (“an actionable FCA conspiracy exists only where at least one of the alleged co-conspirators actually committed an FCA violation”).

**Jury Instruction No. 56:**     **Fourth Element—Damages**

The fourth element of an FCA conspiracy that Plaintiffs must prove by a preponderance of the evidence is that they suffered damages because of the acts of Novartis. As I mentioned before, I will explain this element in depth at the end of these instructions.

For now, I instruct you that Plaintiffs have proven that they suffered damages only if they can demonstrate, by a preponderance of the evidence, that they lost money as a result of the alleged kickback scheme.

AUTHORITY: 31 U.S.C. § 3731(d) (“In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.”); U.S. ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 432 (S.D.N.Y. 1999) (McMahon, J.).

**IV. EXJADE PHASE ONLY: NON-FCA STATE LAW CLAIMS**

**Jury Instruction No. 57: Overview of Non-FCA State Law Claims**

The remaining state claims relate only to Novartis's relationship with BioScrip.

AUTHORITY: First Amended Compl. of the States of Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma and Wisconsin, Sept. 18, 2014, ECF No. 257; State of Washington Compl. in Intervention, Jan. 27, 2014, ECF No. 82.

**Jury Instruction No. 58: Indiana Theft**

The State of Indiana alleges that Novartis is liable for theft in connection with Exjade claims submitted by BioScrip. Theft is defined by Indiana law as follows: A person who knowingly and intentionally exerts unauthorized control over property of another person, with intent to deprive the other person of any part of its value or use, commits theft. In this case, that means that Indiana must prove, by a preponderance of the evidence, that Novartis intentionally or knowingly exerted unauthorized control over the property of the State of Indiana with intent to deprive the State of Indiana of any part of its value or use, and the fair market value was at least \$750.

A person engages in conduct intentionally if, when she engages in the conduct, it is her conscious objective to do so. For the purposes of the Indiana theft count, a person engages in conduct “knowingly” if, when she engages in this conduct, she is aware of a high probability that she is doing so.

The phrase “exert control over property” is defined by Indiana law to include taking property.

The term “property” is defined by Indiana law as meaning anything of value.

As relevant to this case, a person’s control over the property of another person is “unauthorized” if it is exerted by creating or confirming a false impression in the other person or by promising performance that the person knows will not be performed.

If the State of Indiana failed to prove any of these elements by a preponderance of the evidence, you must find Novartis not liable for theft.

AUTHORITY: Ind. Pattern Jury Instructions – Criminal, Instructions No. 4.31, 9.05, 14.81, 14.165, 14.209 (Lexis 2015).

**Jury Instruction No. 59:     Indiana Medicaid Fraud**

The State of Indiana alleges that Novartis is liable for Medicaid Fraud in connection with Exjade claims submitted by BioScrip. Medicaid Fraud is defined by Indiana law as follows.

A person who knowingly or intentionally obtains payment from the Medicaid program under Indiana Code section 12-15 by means of a false or misleading written statement or other fraudulent means commits Medicaid fraud. In addition, a person who knowingly or intentionally conceals information for the purpose of applying for or receiving unauthorized payments from the Medicaid program commits Medicaid fraud.

Before you may find Novartis liable for Medicaid Fraud, the State of Indiana must prove by a preponderance of the evidence that Novartis:

- (1) knowingly or intentionally
- (2) obtained payment from the Medicaid program under Indiana Code section 12-15
- (3) by means of a false or misleading written statement or other fraudulent means, or that Novartis
  - (1) knowingly or intentionally
  - (2) concealed information
  - (3) for the purpose of applying for or receiving unauthorized payments from the Medicaid program.

A person engages in conduct intentionally if, when she engages in the conduct, it is her conscious objective to do so.

If the State of Indiana failed to prove these elements by a preponderance of the evidence, then you must find Novartis not liable for Indiana Medicaid Fraud.

AUTHORITY: Ind. Pattern Jury Instructions – Criminal, Instructions No. 4.58(a2), 4.58(d) (Lexis 2015).

**Jury Instruction No. 60:     New Jersey Conversion**

The State of New Jersey alleges that Novartis is liable for conversion in connection with Exjade claims submitted by BioScrip. To prevail on this count, the State of New Jersey must prove that Novartis:

- (1) intentionally
- (2) exercised unauthorized dominion and control
- (3) over property owned by the State of New Jersey
- (4) that was inconsistent with New Jersey's rights.

If the State of New Jersey has failed to prove these elements by a preponderance of the evidence, then you must find Novartis not liable for conversion.

AUTHORITY: LaPlace v. Briere, 962 A.2d 1139, 1145 (N.J. App. Div. 2009).

**Jury Instruction No. 61:     New York Repeated Fraudulent Acts**

The State of New York alleges that Novartis is liable for repeated fraudulent acts in connection with Exjade claims submitted by BioScrip. To prevail on this count, the State of New York must prove that:

- (1)     Novartis has engaged in repeated fraudulent or illegal acts or otherwise demonstrated persistent fraud or illegality
- (2)     in the carrying on, conducting or transaction of its business.

The words “fraud” or “fraudulent” as used for this count mean any scheme to defraud or any deception, misrepresentation, concealment, suppression or false promise. The terms “persistent fraud” or “illegality” mean continuing fraudulent or illegal conduct. The term “repeated” refers to the repetition of any distinct fraudulent or illegal act, or conduct that affects more than one person.

If the State of New York fails to prove both of these elements by a preponderance of the evidence, then you must find for Novartis on this count.

AUTHORITY: Adapted from N.Y. Exec. Law § 63(12).

**Jury Instruction No. 62:**     **New York Misappropriation of Public Property**

The State of New York alleges that Novartis is liable for misappropriation of public property in connection with Exjade claims submitted by BioScrip. To prevail on this count, the State of New York must prove that:

- (1)     Novartis wrongfully
- (2)     obtained money
- (3)     held or owned by the State of New York.

If the State of New York fails to prove these elements by a preponderance of the evidence, then you must find for Novartis on this count.

AUTHORITY: N.Y. Exec. Law § 63-c(1).

**Jury Instruction No. 63: Maryland Constructive Fraud**

The State of Maryland alleges that Novartis is liable for constructive fraud in connection with Exjade claims submitted by BioScrip. To prevail on this count, the State of Maryland must prove by a preponderance of the evidence that Novartis:

- (1) had a legal or equitable duty to Maryland;
- (2) breached its duty to Maryland;
- (3) and did so in a way that tends to deceive others, to violate public or private confidence, or to injure public interests.

I instruct you that Novartis owed no duty to Maryland unless you find that Maryland has proved by a preponderance of the evidence that Novartis entered into a contract with Maryland.

AUTHORITY: Thompson v. UBS Fin. Servs., Inc., No. 74 Sept. Term 2014, 2015 WL 2448819, at \*11 & n.13 (Md. May 22, 2015); Mem. & Order (“Novartis VI”) at 25-26, Sept. 4, 2014, ECF No. 234 (“Novartis owed no duty to the State of Maryland.” (citations omitted).)

**Jury Instruction No. 64:**     **Illinois, New York and Washington Fraudulent Practices**

The States of Illinois, New York and Washington allege that Novartis is liable for public assistance fraud in connection with Exjade claims submitted by BioScrip. To prevail on these counts, Illinois, New York or Washington must prove by a preponderance of the evidence that:

- (1) Novartis obtained or attempted to obtain payments from the Plaintiff State,
- (2) in a greater amount than that to which it was entitled,
- (3) by making a false statement or a misrepresentation to the State, or by concealing material facts from the State, or by some other fraudulent scheme or device, and
- (4) that (in the case of Illinois) Novartis acted willfully, that (in the case of New York) Novartis acted knowingly, or that (in the case of Washington), Novartis acted both knowingly and willfully.

If the Plaintiff States do not prove all of these elements by a preponderance of the evidence, then you must find for Novartis on these counts.

AUTHORITY: 305 Ill. Comp. Stat. Ann. 5/8A-7 (West 2015); Wash. Rev. Code Ann. § 74.09.210(1)(a)-(c) & (2) (West 2015).

**Jury Instruction No. 65:**     **Washington Tortious Interference with Contract or Business Expectation**

The State of Washington is also alleging that Novartis committed tortious interference with that state's contract or business expectation with BioScrip. To recover on a claim of tortious interference with contract or business expectation, the State of Washington has the burden of proving each of the following elements:

- (1) That at the time of the conduct at issue, the State of Washington was a party to a valid contract with BioScrip to provide drugs for Washington Medicaid or that the State of Washington had a business expectation with a probability of future economic benefit for the State;
- (2) That Novartis knew of the existence of that relationship;
- (3) That Novartis intentionally induced or caused BioScrip to breach the contract or terminate the business expectation with the State of Washington;
- (4) That Novartis's interference was for an improper purpose or by improper means, as I will define; and
- (5) That the conduct of Novartis was a proximate cause of damages to the State of Washington.

For purposes of Washington's tortious interference count, "interference for improper purpose" is interference with an intent to harm the State of Washington.

For the purposes of Washington's tortious interference count, "interference by improper means" is interference that violates a statute, a regulation, a recognized rule of common law or an established standard of the trade or profession.

A cause of an injury is a "proximate cause" if it is related to the injury in both of the following two ways: (1) the cause produced the injury in a direct

sequence unbroken by any superseding cause, and (2) the injury would not have happened in the absence of the cause.

If you find from your consideration of all the evidence that each of these elements has been proven, then your verdict should be for the State of Washington on this count. On the other hand, if you find that any of these propositions has not been proven, your verdict should be for Novartis on this count.

AUTHORITY: Wash. Pattern Jury Instructions—Civil, Instructions 15.01.01, 352.01.01, 352.02, 352.03 (West 2013).

**Jury Instruction No. 66: Common-Law Fraud**

Now I will tell you about another type of violation that some of Plaintiffs are alleging. The States of Maryland, Michigan, New Jersey, Oklahoma and Washington are alleging that Novartis defrauded those States by committing common-law fraud in connection with Exjade claims submitted by BioScrip. To establish common-law fraud, these Plaintiff States have the burden of proving each of the following elements by clear and convincing evidence:

- (1) That Novartis made a material representation to a Plaintiff;
- (2) That the material representation was false;
- (3) That Novartis knew that representation was false or made that representation with reckless disregard for the truth of the representation;
- (4) That Novartis made that representation with the intention that it should be acted upon by that Plaintiff;
- (5) That Plaintiff paid claims in reliance upon the representation; and
- (6) That, as a result of that Plaintiff's reliance upon the statement, it sustained injury.

For purposes of these common law fraud counts only, a false representation of a past or present fact is any words or conduct that create an untrue or misleading impression of the actual past or present fact in the mind of another. To constitute actionable fraud, false representations must generally relate to present or pre-existing fact, and are ordinarily not representations or statements that involve matters that may or may not occur in the future. However, if a promise about the future is made with an intention not to perform it, and is made for the purpose of deceiving the person to whom it was made, and inducing that person to act, such actions constitute fraud.

A fact is material if a reasonably careful person under the circumstances would attach importance to it in determining her course of action.

AUTHORITY: Adapted from Okla. Uniform Jury Instructions-Civil, Instructions 18.1, 18.3, 18.4, 18.8 (West 2014); see White v. Kennedy Krieger Inst., Inc., 110 A.3d 724, 744 (Md. Ct. Spec. App. 2015); Titan Ins. Co. v. Hyten, 817 N.W.2d 562, 567 (Mich. 2012); Banco Popular N. Am. v. Gandi, 876 A.2d 253, 260 (N.J. 2005); Bowman v. Presley, 2009 OK 48, ¶ 13, 212 P.3d 1210, 1218; Elcon Const., Inc. v. E. Wash. Univ., 273 P.3d 965, 970 (Wash. 2012); N.J. Model Civil Jury Charges, Charge 3.30E (West 2015); Mich. Model Civil Jury Instructions, Instruction 128.01 (Lexis 2015); Md. Civ. Pattern Jury Instructions, Instructions 11:1, 11:3 (Lexis 2013); Wash. Pattern Jury Instructions—Civil, Instruction 160.04 (West 2013).

**Jury Instruction No. 67:      Common-Law Civil Conspiracy**

Separate from conspiracy under the False Claims Act, the States of Oklahoma and Washington have alleged that Novartis participated in a common-law civil conspiracy with BioScrip. To establish civil conspiracy, Oklahoma and Washington have the burden of proving by clear and convincing evidence that:

- (1) Novartis entered into an agreement with BioScrip,
- (2) to do an unlawful act or to do a lawful act by unlawful means, and
- (3) either Novartis or BioScrip pursued an independently unlawful purpose or used an independently unlawful means.

If Oklahoma or Washington do not prove all of these elements by clear and convincing evidence, then you must find for Novartis on these counts.

AUTHORITY: Brock v. Thompson, 1997 OK 127, ¶ 39, 948 P.2d 279, 294; Bonneville v. Pierce Cty., 202 P.3d 309, 318 (Wash. Ct. App. 2008).

**Jury Instruction No. 68:**     **Common-Law Fraud and Civil Conspiracy—Clear and Convincing Evidence**

To hold Novartis liable for common-law fraud or civil conspiracy, Plaintiffs must prove each element by clear and convincing evidence. This standard is different from and more demanding than the preponderance of the evidence burden that applies to the other claims. Clear and convincing evidence is evidence that produces in your minds a firm belief or conviction that the allegations sought to be proved by the evidence are true. It is evidence so clear, direct, weighty in terms of quality and convincing as to cause you to come to a clear conviction of the truth of the precise facts in issue.

The clear and convincing standard of proof requires that the result shall not be reached by a mere balancing of doubts or probabilities, but rather by clear evidence which causes you to be convinced that the allegations sought to be proved are true.

AUTHORITY: Adapted from Charge 1.19, N.J. Model Civil Jury Charges (West 2015).

**Jury Instruction No. 69:     Damages**

You should not infer that Plaintiffs are entitled to recover damages merely because I am instructing you on the elements of damages. I am instructing you on damages because, as I explained earlier, it is an element of Plaintiffs' FCA claims and also so that you will have guidance should you decide that Plaintiffs are entitled to recovery.

AUTHORITY: Adapted from Jury Instruction No. 43, U.S. ex rel. Bunk v. Gosselin Worldwide Moving, N.V., No. 1:02-cv-1168 (E.D. Va. Aug. 1, 2014) (Ex. 2) (ECF No. 1312-3), appeal docketed, Nos. 15-1088, 15-1207 (4th Cir. 2015).

**Jury Instruction No. 70: Calculation of Damages**

[Exjade phase: Plaintiffs must prove that its damages were caused by Novartis's acts. For Exjade, that means that a patient was influenced to purchase or to order Exjade that he or she would not have purchased or ordered if Novartis had not paid or offered kickbacks.

The measure of Plaintiffs' damages is the net amount that they paid out because of the alleged kickback scheme above what they would have paid if there had been no kickback scheme. In other words, if you find that there was a kickback scheme, you cannot base damages on any payments that would have been made had there been no kickback scheme.]

[Myfortic phase: Plaintiffs must prove that its damages were caused by Novartis's acts. For Myfortic, that means that a doctor was influenced to prescribe Myfortic that he or she would not have prescribed if Novartis had not paid or offered kickbacks.

The measure of Plaintiffs' damages is the net amount that they paid out because of the alleged kickback scheme above what they would have paid if there had been no kickback scheme. In other words, if you find that there was a kickback scheme, you cannot base damages on any payments that would have been made had there been no kickback scheme.

Plaintiffs have argued that CellCept or generic MMF would have been prescribed in certain cases had there been no alleged kickback scheme. If you find a kickback scheme and Novartis liable, damages would be the amount that Plaintiffs paid out for Myfortic because of the alleged kickback scheme above what they would have paid for CellCept or generic MMF had there been no kickback scheme.]

AUTHORITY: United States v. Rapoport, 514 F. Supp. 519, 525 (S.D.N.Y. 1981); U.S. ex rel. Longhi v. United States, 575 F.3d 458, 473 (5th Cir. 2009); United States v. Miller, 645 F.2d 473, 475-76 (5th Cir. 1981); United States v. Hibbs, 568 F.2d 347, 349 (3d Cir. 1977); see also United States v. Wells Fargo Bank, N.A., 972 F. Supp. 2d 593, 625 (S.D.N.Y. 2013); United States v. Bornstein, 423 U.S. 303, 316 n.13 (1976).

**Jury Instruction No. 71:     Burden of Proof for Damages**

Plaintiffs have the burden of proving damages by a preponderance of the evidence.

AUTHORITY: Adapted from Jury Instruction No. 45, U.S. ex rel. Bunk v. Gosselin Worldwide Moving, N.V., No. 1:02-cv-1168 (E.D. Va. Aug. 1, 2014) (Ex. 2) (ECF No. 1312-3), appeal docketed, Nos. 15-1088, 15-1207 (4th Cir. 2015); 31 U.S.C. § 3731(d).

**Jury Instruction No. 72:**     **Reasonable Proof Required**

Plaintiffs must prove their damages with reasonable certainty. You may only award Plaintiffs damages that are not speculative. Speculative damages are those that might be possible but are remote or based on guesswork.

If you should find that Plaintiffs are entitled to a verdict, you may award Plaintiffs only such damages as will reasonably compensate them for such injury and damage as you find, by a preponderance of evidence, Plaintiffs have sustained because of Novartis's conduct.

Plaintiffs are not required to prove the exact amount of its damages, but must show sufficient facts and circumstances to permit you to make a reasonable estimate of the damages. If Plaintiffs fail to do so, then they cannot recover.

AUTHORITY: Jury Instruction No. 46, U.S. ex rel. Bunk v. Gosselin Worldwide Moving, N.V., No. 1:02-cv-1168 (E.D. Va. Aug. 1, 2014) (Ex. 2) (ECF No. 1312-3), appeal docketed, Nos. 15-1088, 15-1207 (4th Cir. 2015).

**Jury Instruction No. 73: Calculation of Penalties**

If you find that Novartis violated the False Claims Act, you must determine the specific number of acts Novartis committed that caused a violation of the False Claims Act for which Plaintiffs have proven all elements. Plaintiffs must identify the specific acts they contend Novartis committed that caused violations of the False Claims Act.

The number of acts would properly be based on the acts of Novartis, not the acts of any other entities. For example, if Novartis engaged in one act that caused a specialty pharmacy to submit 10 false claims, the number of penalties would be one based on the single act of Novartis, not the 10 false claims submitted by the specialty pharmacy.

AUTHORITY: 31 U.S.C. § 3729(a); United States v. Bornstein, 423 U.S. 303, 313 (1976); U.S. ex rel. Kreindler & Kreindler v. United Technologies Corp., 985 F.2d 1148, 1157 (2d Cir. 1993); U.S. ex rel. Hays v. Hoffman, 325 F.3d 982, 993 (8th Cir. 2003); United States v. Krizek, 111 F.3d 934, 939-40 (D.C. Cir. 1997) (collecting cases).

**V. GENERAL DELIBERATION INSTRUCTIONS**

**Jury Instruction No. 74: Right To See Exhibits and Hear Testimony;  
Communications with Court**

You are about to go into the jury room and begin your deliberations. If during those deliberations you want to see any of the exhibits, you may request that they be brought into the jury room. If you want any of the testimony read back to you, you may also request that. Please remember that it is not always easy to locate what you might want, so be as specific as you possibly can in requesting exhibits or portions of the testimony.

Your requests for exhibits or testimony—in fact any communication with the Court—should be made to me in writing, signed by your foreperson, and given to one of the marshals. In any event, do not tell me or anyone else how the jury stands on any issue until after a unanimous verdict is reached.

AUTHORITY: Instruction 78-1, Modern Federal Jury Instructions—Civil (LexisNexis 2009 ed.).

**Jury Instruction No. 75: Duty To Deliberate/Unanimous Verdict**

You will now return to the jury room decide the case. In order to prevail, Plaintiffs must sustain their burden of proof as I have explained to you with respect to each element of the claim. If you find that Plaintiffs have succeeded, you should return a verdict in his or her favor on that claim. If you find that Plaintiffs failed to sustain the burden on any element of the claim, you should return a verdict against Plaintiffs.

It is your duty as jurors to consult with one another and to deliberate with a view to reaching an agreement. Each of you must decide the case for himself or herself, but you should do so only after a consideration of the case with your fellow jurors, and you should not hesitate to change an opinion when convinced that it is erroneous. Your verdict must be unanimous, but you are not bound to surrender your honest convictions concerning the effect or weight of the evidence for the mere purpose of returning a verdict or solely because of the opinion of other jurors. Discuss and weigh your respective opinions dispassionately, without regard to sympathy, without regard to prejudice or favor for either party, and adopt that conclusion which in your good conscience appears to be in accordance with the truth.

Again, each of you must make your own decision about the proper outcome of this case based on your consideration of the evidence and your discussions with your fellow jurors. No juror should surrender his or her conscientious beliefs solely for the purpose of returning a unanimous verdict.

AUTHORITY: Instruction 78-3, Modern Federal Jury Instructions—Civil (LexisNexis 2009 ed.) (citing Am. Pub. Co. v. Fisher, 166 U.S. 464 (1896); Grace Lines, Inc. v. Motley, 439 F.2d 1028 (2d Cir. 1971)).

**Jury Instruction No. 76:     Special Verdict Form**

I have prepared a special verdict form for you to use in recording your decision. The special verdict form is made up of questions concerning the important issues in this case. These questions are to be answered “yes” or “no” unless otherwise indicated. Your answers must be unanimous and must reflect the conscientious judgment of each juror. You should answer every question except where the verdict form indicates otherwise.

AUTHORITY: Instruction 78-9, Modern Federal Jury Instructions—Civil (LexisNexis 2009 ed.).

**Jury Instruction No. 77:**     **Return of Verdict**

After you have reached a verdict, your foreperson will fill in the form that has been given to you, sign and date it and advise the marshal outside your door that you are ready to return to the courtroom.

I will stress that each of you should be in agreement with the verdict which is announced in court. Once your verdict is announced by your foreperson in open court and officially recorded, it cannot ordinarily be revoked.

AUTHORITY: Instruction 78-6, Modern Federal Jury Instructions—Civil (LexisNexis 2009 ed.).

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Respectfully submitted,

/s/ Evan R. Chesler

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